



**UNITED STATES DEPARTMENT OF COMMERCE**  
**Patent and Trademark Office**

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*ID*

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/257,650	02/25/99	FUJINO	M 48194

HM32/1004  
DIKE, BRONSTEIN, ROBERTS & CUSHMAN  
130 WATER STREET  
BOSTON MA 02109

EXAMINER

O HARA, E

ART UNIT	PAPER NUMBER
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1646

*16*

DATE MAILED: 10/04/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/257,650**

Applicant(s)

**Fujino et al.**

Examiner

**Eil en B. O'Hara**

Group Art Unit

**1646**



☒ Responsive to communication(s) filed on Jul 17, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-14, 16-19, 21-24, and 26 is/are pending in the application

Of the above, claim(s) 1-13 is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 14, 16-19, 21-24, and 26 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-14, 16-19, 21-24, and 26 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

1. Claims 1-14, 16-19, 21-24 and 26 are pending in the instant application. Claims 14, 16-19, 21-24 and 26 have been amended and claims 15, 20 and 25 have been canceled as requested by Applicant in Paper Number 15, filed July 17, 2000.

### ***Response to Amendment***

2.1 The reply filed on July 17, 2000 is not fully responsive to the prior Office action and the amendment to claim 14 has not been entered, because claim 14 has been improperly amended. In the amended claim on line 3, "a" was replaced by "an", but "an" was originally in the claim.

2.2 The amendment to claim 21 has also been improperly amended. On line 7 of the amended claim, the word "product" in brackets never occurred in the original claim. Also on line 7 the word "said" in the original claim is not present in the amended claim. Also, on lines 4-5 of the original claim, the term "on the aberrant receptor" does not appear in the amended claim.

2.3 Claims 14 and 21 need to be properly amended in the response to this Office Action to be entered.

### ***Withdrawn Rejections***

3.1 The rejection of claims under 112 § 1 is withdrawn in view of Applicant's amendment.

3.2 The rejections of claims under 112 § 2, with the exception of those that are maintained as discussed below, are withdrawn in view of Applicant's amendment.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 22 and 23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 22 recites “the aberrant receptor is **isolated** from a cell”, but it is dependent upon claim 21 which encompasses a method in which a substance is assayed for its activity on the signal transduction system of a cell having the aberrant receptor. In order to assay the activity of the receptor in the signal transduction system, the cell must be intact in order to have all of the different molecules that comprise the signal transduction system available and in the correct biological compartments. This method is not enabled with a receptor that is isolated from a cell and the other components of the signal transduction system.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 14, 16, 18, 19, 21-23, 24 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5.1 The rejections of claims 14, 16, 21, 24, 26 and dependent claims 18, 19, 22, 23 and 26 as being vague and indefinite because they recite terms that include the words “operate”, “operating” or “operation”, are maintained. Applicant argues that the specification clearly describes what is mean by the terms comprising operate, operating or operation, and cites as example page 15, lines 19-24 of the specification. Applicant’s arguments have been fully considered but are not found persuasive. Though there are passages in the specification using these terms, they are not terms that are recognized in the art as having those activities.

5.2 Claim 16 is indefinite because it recites the limitation "said product" and there is no antecedent basis for this limitation in the claim.

5.3 Claims 19 and 23 are indefinite because they encompass a method for screening substances in which a further step comprises selecting the receptor by comparing “a” gene isolated from a mammal suffering from a disease with “a” gene from a mammal that does not carry the aberrant receptor, and does not specify that the gene actually encode the receptor, so “a gene” could mean any gene from the mammal.

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5.4 Claim 21 is indefinite because it encompasses a method for preparing a substance for treatment of a disease in which the final step is preparing the selected substance in a pharmaceutical composition, and preparing a substance does not explain how to prepare a substance. It is suggested that “preparing the selected substance in a pharmaceutical composition” be replaced by something such as “admixing the selected substance with a pharmaceutically acceptable carrier”.

5.5 Claim 26 is indefinite because it is not clear if the substance normally operates the wild type receptor, or the aberrant receptor.

5.6 Claim 26 is also indefinite because if the substance normally operates or activates the wild type receptor, but also can operate the aberrant receptor, then by definition the receptor can't be aberrant, because it is activated by the natural ligand.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The rejection of claims 14-25 under 35 U.S.C. 102(b) as being anticipated by Lebrun et al., The Journal of Biological Chemistry, Vol. 268, No. 15, pages 11272-11277, May 25, 1993, is maintained.

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The teachings of Lebrun et al. were discussed in the previous Office Action. Applicant argues that Lebrun et al. does not anticipate the present invention because Lebrun et al. show that the mutation in the insulin receptor does not affect the insulin binding activity and the intrinsic kinase of the Val382, and that the insulin binding to the receptor cannot simulate (stimulate?) the kinase activity of the mutant receptor. Applicant further argues that the monoclonal antibodies of Lebrun act like an “enhance” or “helper”, which enables the mutant receptor to act in the presence of insulin binding to the mutant receptor, and this method of action is much different from the presently claimed method of screening for a substance capable of restoring the activity of the receptor, which is capable of operating a mutant receptor by itself, and further, that the methods of the present invention can select a substance capable of restoring the activity of a mutant receptor without changing the conformation of the receptor, in contrast to the mechanisms described in Lebrun et al.

Applicant’s arguments have been fully considered but are not found persuasive. To address the first point, that the mutation in the insulin receptor does not affect the insulin binding activity and the intrinsic kinase activity of the Val382, and so does not anticipate the present invention, there is no limitation in the claims that requires that the natural ligand must not be able to bind to the receptor, or bind with changed affinity, or that another activity of the receptor (kinase activity) must also be defective. The claims encompass a method of screening for a substance that will restore activity to an aberrant receptor, and the monoclonal antibodies of

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Lebrun et al. were identified because they restored activity to the non-active insulin receptor disclosed in the reference.

Similarly, there is no limitation in the claims that requires that the substance being screened has to be a natural ligand, agonist or antagonist, or that the substance must be able to restore activity to the receptor by itself, in the absence of the natural ligand or any other compound. The claims merely encompass a method of screening for a substance that will restore activity to an aberrant receptor by assaying the activity of the receptor in the presence of the substance. The method of screening for the monoclonal antibodies of Lebrun et al. therefore meets the limitations of the claims as written.

There is also no limitation in the claims that the substance being screened should not change the conformation of the aberrant receptor.

Thus, because the limitations argued by Applicant are not recited in the claims, Lebrun et al. anticipate the claims as written, and the rejection is maintained.

### ***Conclusion***

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.



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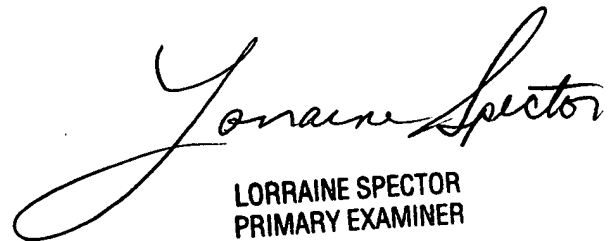
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Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D

Patent Examiner



LORRAINE SPECTOR  
PRIMARY EXAMINER